(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 17 February 2005 (17.02.2005)

PCT

(10) International Publication Number WO 2005/013935 A2

(51) International Patent Classification7:

A61K 9/00

(21) International Application Number:

PCT/EP2004/008843

- (22) International Filing Date: 6 August 2004 (06.08.2004)
- (25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 60/493,388

7 August 2003 (07.08.2003) US

- (71) Applicant (for all designated States except US): SB PHARMCO PUERTO RICO INC. [US/US]; The Prentice Hall Corp. System of P.R. Inc., c/o FGR Corporate Services Inc., BBV Tower, 8th Floor, 254 Munoz Rivera Avenue (PR).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): HOKE, John, Francis [US/US]; GlaxoSmithKline, Five Moore Drive, Research Triangle Park, NC 27709 (US). MARTINI, Luigi [GB/GB]; GlaxoSmithKline, New Frontiers Science Park South, Third Avenue, Harlow Essex CM19 5AW (GB). RE, Vincenzo [GB/GB]; GlaxoSmithKline, New Frontiers Science Park South, Third Avenue, Harlow Essex CM19 5AW (GB). SALE, Mark, Edward [US/US]; GlaxoSmithKline, Five Moore Drive, Research Triangle Park, North Carolina 27709 (US).

- (74) Agent: GIDDINGS, Peter, John; GlaxoSmithKline, Corporate Intellectual Property (CN925.1), 980 Great West Road, Brentford Middlesex TW8 9GS (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

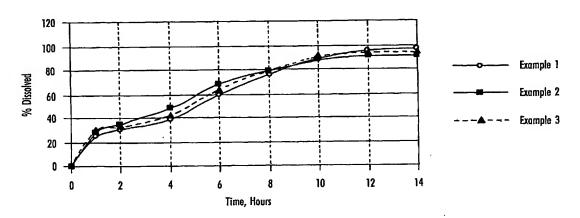
Published:

 without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: NOVEL COMPOSITION

Dissolution profiles for examples 1, 2 and 3



(57) Abstract: An oral dosage form comprising a first composition and a second composition, each composition comprising a pharmaceutically acceptable weak base, especially Compound A or a pharmaceutically acceptable salt or solvate thereof, ('the drug') and a pharmaceutically acceptable carrier therefor, wherein the first and second compositions are arranged to release drug at differing release rates on administration such that the rate of release of the drug from the dosage form is substantially independent of pH; a process for preparing such a dosage form and the use of such a dosage form in medicine.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(19) World Intellectual Property Organization International Bureau



] (1811-1816) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (1814-181) | (18

(43) International Publication Date 17 February 2005 (17.02.2005)

PCT

(10) International Publication Number WO 2005/013935 A3

- (51) International Patent Classification7: A61K 9/20, 9/28
- (21) International Application Number:

PCT/EP2004/008843

- (22) International Filing Date: 6 August 2004 (06.08.2004)
- (25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/493,388

7 August 2003 (07.08.2003) US

- (71) Applicant (for all designated States except US): SB PHARMCO PUERTO RICO INC. [US/US]; The Prentice Hall Corp. System of P.R. Inc., c/o FGR Corporate Services Inc., BBV Tower, 8th Floor, 254 Munoz Rivera Avenue (PR).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): HOKE, John, Francis [US/US]; GlaxoSmithKline, Five Moore Drive, Research Triangle Park, NC 27709 (US). MARTINI, Luigi [GB/GB]; GlaxoSmithKline, New Frontiers Science Park South, Third Avenue, Harlow Essex CM19 5AW (GB). RE, Vincenzo [GB/GB]; GlaxoSmithKline, New Frontiers Science Park South, Third Avenue, Harlow Essex CM19 5AW (GB). SALE, Mark, Edward [US/US]; GlaxoSmithKline, Five Moore Drive, Research Triangle Park, North Carolina 27709 (US).

- (74) Agent: GIDDINGS, Peter, John; GlaxoSmithKline, Corporate Intellectual Property (CN925.1), 980 Great West Road, Brentford Middlesex TW8 9GS (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

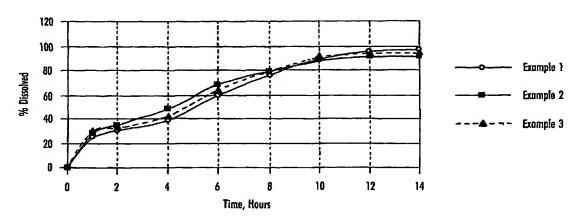
Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: COMPOSITION FOR RELEASING A WEAK BASE FOR AN EXTENDED PERIOD OF TIME

Dissolution profiles for examples 1, 2 and 3



(57) Abstract: An oral dosage form comprising a first composition and a second composition, each composition comprising a pharmaceutically acceptable weak base, especially Compound A or a pharmaceutically acceptable salt or solvate thereof, ('the drug') and a pharmaceutically acceptable carrier therefor, wherein the first and second compositions are arranged to release drug at differing release rates on administration such that the rate of release of the drug from the dosage form is substantially independent of pH; a process for preparing such a dosage form and the use of such a dosage form in medicine.

(88) Date of publication of the international search report: 14 July 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.